

Attachment #3: Background

The Central Institutional Review Board (CIRB) Initiative is a project of the National Cancer Institute (NCI) to develop and implement a centralized model of IRB review for multi-site, NCI-sponsored clinical trials. The goal of the Initiative is two-fold:

- A. To streamline regulatory compliance and decrease the duplicative burden of protocol review that currently occurs at hundreds of local IRBs nationwide by providing a single, centralized review that can be utilized by local IRBs participating in NCI-sponsored multi-center trials.
- B. To maintain and enhance the protection of research participants by providing consistent, expert IRB review at the national level.

Currently, the Initiative involves three CIRBs, the Adult CIRB – Late Phase Emphasis reviewing adult NCI-sponsored primarily Phase 3 treatment trials, the Adult CIRB – Early Phase Emphasis reviewing adult NCI-sponsored Phase 0, 1, 2 treatment trials and the PedCIRB reviewing NCI-sponsored pediatric Phase 0, 1, 2, 3, and pilot treatment trials. The CIRB uses an independent model of IRB review where a local institution and principal investigators inform the CIRB about local context considerations, including local laws and requirements, via the submission of annual worksheets. Each CIRB reviews the NCI-sponsored trials within their purview and additionally review the local context considerations for each institution with investigators credentialed to participate in those trials.

The NCI recruits and appoints individuals to serve on the CIRB. The Adult CIRB – Late Phase Emphasis has been providing reviews since January 2001. The pediatric CIRB began reviewing studies in the fall of 2004. The Adult CIRB – Early Phase Emphasis began reviewing studies in the late summer of 2013. Both Adult CIRBs meet twice a month with the PedCIRB meeting once per month. Originally, the adult CIRB was meeting once a month in Bethesda. In order to decrease the travel burden on CIRB members and to increase the frequency of meetings, a web-based meeting tool called ePanel© was implemented ePanel© was developed by another NCI contractor and allows the meetings to be convened via an internet-assisted conference call (please see <http://www.ePanel3.org>). CIRB members can stay at home and meet in cyberspace using a combination of telephone and desktop/laptop. In-person meetings, designed to provide training and to facilitate interactions, are currently planned once per year in Rockville. The three CIRBs utilize ePanel for all meetings.

History of Contract

The current contractor is the Emmes Corporation.

Contract Number: HHSN261200800010C

Period of Performance: June 20, 2008 – August 19, 2014

The contract prior to this was awarded to Capital Technology Information Services.
Contract Number N02-CM-52211
POP: June 20, 2005 – June 19, 2008

The contract prior to this was held by WESTAT.
Contract Number N02-CM-97024
POP: September, 30, 1999 – June 19, 2005

For more detailed background information on the CIRB Initiative please see
<http://www.ncicirb.org>.